K112839

NOV 14 2011

510(k) Summary

The information below is provided for the Varian High Energy Linear Accelerator, following the format of 21 CFR 807.92.

1. Submitter:

Varian Medical Systems
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Palo Alto, CA 94304
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2. Name of the Device: Varian High Energy Linear Accelerator

Trade / Proprietary Names:
Novalis Tx, Trilogy, Trilogy Tx
Clinac iX, Clinac Cx
Clinac 2100C, 2100 C/D, 2300 C/D
Clinac 21 EX, 23 EX
Clinac DHX, DMX

Common or Usual Names:
Novalis Tx, Trilogy, Trilogy Tx
Clinac iX, Clinac Cx
Clinac 2100C, 2100 C/D, 2300 C/D
Clinac 21 EX, 23 EX
Clinac DHX, DMX

Classification Name:
Medical Charged Particle Radiation Therapy System
21 CFR §892.5050
Class II

Product Code: 90 IYE

3. Predicate Device:
Varian High Energy Linear Accelerator K100890

4. Description of the Device:

The Varian High Energy Linear Accelerator models provide various selections among the features, specifications, and accessories that have been most recently cleared as the Varian High Energy Linear Accelerator, K100890.

The changes to the Varian High Energy Linear Accelerator provide support for treatments using the high intensity photon treatment mode, also known as FFF (Flattening Filter Free). Additionally, couch motion rules are modified to enable the use of patient support systems where the targeted anatomy and the treatment isocenter area below the surface of the couch top. Modifications that augment existing safety controls are also included.

All other features of the Varian High Energy Linear Accelerator models remain as cleared by K100890.

5. Intended Use Statement

The Varian High Energy Linear Accelerator is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

6. Indications for Use Statement

The Varian High Energy Linear Accelerator is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

7. Substantial Equivalence

The modified device, the Varian High Energy Linear Accelerator, is substantially equivalent to the predicate device, the Varian High Energy Linear Accelerator (K100890).

The intended use and indications for use for the device are unchanged – see items 5 and 6 above.

The functionality of the Varian High Energy Linear Accelerator is equivalent to the functionality of the Varian predicate device in safety and effectiveness. Compared with the predicate device, the Varian High Energy Linear Accelerator (K100890), the basic operation is the same.

The comparison table below illustrates the substantial equivalence of the cleared device, Varian High Energy Linear Accelerator (K100890) and the modified device, Varian High Energy Linear Accelerator.

Feature and/or Specification	**Cleared Device (High Energy Linear Accelerator K100890)**	**Device with Change (High Energy Linear Accelerator)**
Release version of control software	C-Series 8.0	C-Series 9.0
For gantry rotation from outside the treatment room, collision protection between the gantry & couch, when the couch is outside the boundary conditions set by the user	motion rules are enforced when the imaging arms are extended	motion rules are enforced whether the imaging arms are extended or retracted
Extended Travel Range Zone includes the 10 cm additional height needed to support the Third-party Prone Breast Couch Insert	No	Yes
Interlock preventing additional dose from being delivered after beam hold has been set	Hardware control	Hardware control plus additional secondary software check
Software and hardware support for FFF / HIM (Flattening Filter Free/High Intensity Mode)	No	Yes
Maximum rate at which dose delivery occurs for 10x photon energy	600 MU per minute	600 MU per minute

Feature and/or Specification	Cleared Device (High Energy Linear Accelerator K100890)	Device with Change (High Energy Linear Accelerator)
Maximum rate at which dose delivery occurs for 10x FFF photon energy	None	2400 MU per minute
Maximum rate at which dose delivery occurs for 6x SRS photon energy	1000 MU per minute	1000 MU per minute
Maximum rate at which dose delivery occurs for 6x FFF photon energy	None	1400 MU per minute
Maximum field size	3D Conformal Radiation Therapy: 40cm x 40cm. IMRT: 34cm x 40cm. SRS: 15cm x 15cm	3D Conformal Radiation Therapy: 40cm x 40cm. IMRT: 34cm x 40cm. SRS: 15cm x 15cm
Maximum allowable dose limit for fixed X treatment type (for non-SRS and non-FFF treatment types)	1999 MU	1999 MU
Maximum programmable dose	9999 MU	9999 MU

8. Summary of Performance Testing

The design control procedures applied to the development of the Varian High Energy Linear Accelerator include requirements reviews, risk analysis, and verification and validation testing.

The verification and validation testing results from bench testing support the substantial equivalence of the modified device with its predicate, the unmodified device. Testing included testing against functional requirements, validation of use cases, hazard mitigation and control testing, and testing for compliance with applicable international medical device standards including the general safety standard IEC 60601-1, the electromagnetic compatibility standard IEC 60601-1-2, and the medical accelerator safety standard IEC 60601-2-1.

The objectives of the testing were to ensure that the pre-defined acceptance criteria and pass/fail criteria were met, including all specifications, functional requirements, use cases, hazard mitigations, and compliance with applicable international standards.

The conclusion from the results of the performance testing summarized above is that the defined criteria have been met, and that the specifications have been substantiated by the testing. The table in item 7 presents the key specifications relevant to the modifications for the Varian High Energy Linear Accelerator.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vy Tran
Vice President of Regulatory Affairs and Quality Systems
Varian Medical Systems
3100 Hansen Way, M/S E-110
PALO ALTO CA 94304-1129

NOV 14 2011

Re: K112839
Trade/Device Name: Varian High Energy Linear Accelerator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 26, 2011
Received: September 28, 2011

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112839

Device Name: Varian High Energy Linear Accelerator

Indications for Use:

The Varian High Energy Linear Accelerator is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112839